DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 211, 700, and 800

[Docket Nos. 82N-0330 and 82N-0332]

Tamper-Resistant Packaging Requirements for Certain Over-the-Counter Human Drug and Cosmetic Products and Contact Lens Solutions and Tablets; Stay of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; stay of effective date.

SUMMARY: The Food and Drug Administration (FDA) announces that, in response to a citizen petition, the provision of the tamper-resistant packaging regulations that requires a specific label reference to any identifying characteristic that is incorporated into the tamper-resistant feature of a particular product is stayed until February 6, 1984. Elsewhere in this issue of the Federal Register, the agency announces the availability of the advisory opinion, issued in response to the citizen petition, and also advises that as part of its Tamper-Resistant Packaging Compliance Program, it plans to maintain a current list of acceptable technologies and those packaging technologies that the agency believes are unacceptable and have problems.

DATE: The amendments are effective August 19, 1983. The provisions in §§ 211.132(c), 700.25(c), and 800.12(c) that require that a label reference any identifying characteristic that is incorporated into the tamper-resistant feature are stayed until February 6, 1984.

FOR FURTHER INFORMATION CONTACT: Paul O. Fehnel, National Center for Drugs and Biologics (HFN-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 5, 1982 (47 FR 50442), FDA published regulations establishing tamper-resistant packaging and labeling requirements for certain over-the-counter (OTC) human drug and cosmetic products. In the same issue of the Federal Register (47 FR 50452), the agency also published tamper-resistant regulations for contact lens solutions and tablets. In the Federal Register of April 19, 1983 (48 FR 16658), the agency amended its tamper-resistant packaging and labeling regulations for OTC drug and cosmetic products to clarify certain sections of the preamble and to specify in the regulations those products that the agency had exempted from those regulations. In the same issue of the Federal Register (48 FR 16665), the agency made similar clarifying amendments for contact lens solutions and tablets. One of the clarifying labeling amendments added by the April 19, 1983 rule was the statement, "If the tamper-resistant feature chosen to meet the requirement in paragraph (b) of this section is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement."

The agency received a petition from The Proprietary Association (PA) requesting a stay of the effective date of a portion of the tamper-resistant packaging and labeling regulations. Specifically, PA sought a stay of that provision of the regulations that requires a specific label reference to any identifying characteristic that is incorporated into the tamper-resistant feature of a particular product. For OTC drugs, this statement is required by 21 CFR 211.132(c); and for cosmetic products and contact lens solutions and tablets, 21 CFR 700.25(c) and 800.12(c), respectively, as amended April 19, 1983.

The agency agreed with the petitioner that additional time should be provided to comply with the requirement that any identifying characteristic of the tamper-resistant feature be specifically referred to in the labeling and stayed the effective date for this requirement until February 6, 1984. The petition response was made an advisory opinion. Elsewhere in this issue of the Federal Register, FDA is announcing the availability of the advisory opinion and also of information on packaging technologies.

List of Subjects

21 CFR Part 211

Drugs, manufacturing, Labeling, Laboratories, Packaging and containers, Warehouses.

21 CFR Part 700

Cosmetics, Definitions, Prohibited cosmetic ingredients.

21 CFR Part 800

Administrative detention, Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 501, 502, 505, 506, 507, 601, 602, 701, 52 Stat. 1041 as amended, 1049-1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 361, 362, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 211, 700, and 800 are amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. Part 211 is amended in § 211.132 by revising paragraph (g)(2), to read as follows:

§ 211.132 Tamper-resistant packaging requirements for over-the-counter human drug products.

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(g) * * *

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each affected OTC drug product packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected OTC drug product packaged for retail sale on or after that date.

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PART 700—GENERAL

2. Part 700 is amended in § 700.25 by revising paragraph (e)(2), to read as follows:

§ 700.25 Tamper-resistant packaging requirements for cosmetic products.

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(e) * * *

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each affected cosmetic product packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected cosmetic product packaged for retail sale on or after that date.

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PART 800—GENERAL

3. Part 800 is amended in § 800.12 by revising paragraph (f)(2), to read as follows:

§ 800.12 Contact lens solutions and tablets; tamper-resistant packaging.

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(f) * * *

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each product subject to this section packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected product subject to this section packaged for retail sale on or after that date.

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Effective date. August 19, 1983.

(Secs. 201(n), 501, 502, 505, 506, 507, 601, 602, 701, 52 Stat. 1041 as amended, 1049–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 321(n), 351, 352, 355, 356, 357, 361, 362, 371))

Dated: August 11, 1983.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

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